PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

28 FEB 2005

Applicant's or agent's file reference 2732.107003	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US03/27841	International filing date *(day/month/year)* 04 September 2003 (04.09.2003)	Priority date *(day/month/year)* 04 September 2002 (04.09.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 38/16, 31/715; C07K 16/00 and US Cl.: 514/8, 54; 530/387.2, 388.2, 388.8		
Applicant BIOPOLYMER ENGINEERING, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
16 March 2004 (16.03.2004)	06 December 2004 (06.12.2004)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Dorothea Lawrence for Rebecca Cook Telephone No. 571-272-1600

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International applicati[redacted]

PCT/US03/27841

I. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed.

☒ the description:
pages 1-39 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the claims:
pages NONE, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages 40-42, filed with the letter of 03 November 2004 (03.11.2004)

☒ the drawings:
pages 1-19, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☐ the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages NONE

☐ the claims, Nos. NONE

☐ the drawings, sheets/~~fig~~ NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY [redacted]AMINATION REPORT

International applicati[redacted]
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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims 1-18	YES
	Claims NONE	NO
Inventive Step (IS)	Claims 1-18	YES
	Claims NONE	NO
Industrial Applicability (IA)	Claims 1-18	YES
	Claims NONE	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-18 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method of suppressing or eliminating tumor cells using insoluble .beta.(1,3, 1,6) whole glucan particles and at least one complement activating anti-tumor antibody .

Claims 1-18 meet the criteria set out in PCT Article 33(4), and thus find industrial applicability because the subject matter claimed can be made or used in industry.

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We claim:

1. A method of suppressing or eliminating tumor cells, comprising: administering to a subject in need of treatment a therapeutically effective amount of insoluble β (1,3; 1,6) whole glucan particles and at least one complement activating anti-tumor antibody; wherein the glucan and antibody suppresses or eliminates tumor cells.

2. The method of claim 1, wherein the antibody is introduced via direct administration of a monoclonal or polyclonal antibody or produced via a cancer vaccine.

3. The method of claim 1, wherein the antibody is selected from the group consisting of: trastuzumab, rituximab, cetuximab and combination thereof.

4. The method of claim 1, wherein whole glucan particles and antibody provide a synergistic antitumor effect.

5. The method of claim 1, wherein the whole glucan particles are administered orally.

6. The method of claim 1, wherein the whole glucan particle is administered parenterally.

7. The method of claim 1, wherein the whole glucan particle is derived from yeast.

8. The method of Claim 1, wherein the whole glucan particle is derived from a fungal source.

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9. The method of Claim 8, wherein the fungal source is mushroom.

10. Use of insoluble β (1,3; 1,6) whole glucan particles and complement activating anti-tumor antibody for the manufacture of a medicament for use in treating a neoplastic cell, wherein the combination of glucan and antibody retards the growth of the cell.

11. A method of treating a neoplastic cell comprising administering to said cell a therapeutically effective dose of insoluble β (1,3;1,6) whole glucan particles and a complement activating antibody specific to the neoplastic cell.

12. The method of Claim 11, wherein the combination of glucan and antibody retards the rate of growth of the cell.

13. The method of Claim 11, wherein the combination of glucan and antibody inhibits the growth of the neoplastic cell.

14. The method of Claim 11, wherein the combination of glucan and antibody extends the survival time of a host of the neoplastic cell.

15. The method of Claim 1, wherein the complement activating antibody is coated on tumor cells and activates complement via iC3b deposition on the tumor cells.

16. The method of Claim 15, wherein the whole glucan particle is taken up by macrophages, degraded and the degraded fragments bind to neutrophils in the bone marrow and through chemotaxis migrate and bind to antibody coated tumor cells where complement has been activated via iC3b deposited the tumor cells.

IPEA/US

17. A method of suppressing or eliminating tumor cells, comprising: administering to a subject in need of treatment a therapeutically effective amount of insoluble β (1,3;1,6) whole glucan particles wherein the whole glucan particles is taken up by macrophages, degraded and the degraded fragments bind to neutrophils in the bone marrow and through chemotaxis migrate and bind to antibody coated tumor cells where complement has been activated via iC3b deposited the tumor cells by a naturally occurring complement activating antibody, wherein the binding of glucan to the iC3b tumor cells results in suppressing or eliminating the tumor cells.

18. A method of suppressing or eliminating tumor cells, comprising: administering to a subject in need of treatment a therapeutically effective amount of insoluble β (1,3; 1,6) whole glucan particles and at least one complement activating anti-tumor antibody; wherein the glucan and antibody suppresses or eliminates tumor cells and provided that the glucan is not derived from barley.